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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,246	09/12/2006	Mark L. Lawrence	028186.61646	5820

28172 7590 01/28/2010  
BUTLER, SNOW, O'MARA, STEVENS & CANNADA PLLC  
6075 POPLAR AVENUE  
SUITE 500  
MEMPHIS, TN 38119

EXAMINER
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NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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01/28/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/541,246	<b>Applicant(s)</b> LAWRENCE ET AL.	
	<b>Examiner</b> Mark Navarro	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 December 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 26-30,33,46-49,52-56,59-62,65-68,71-76 and 79-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,9-12,21-25,35-38 and 41-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims pending in the application are 1-5,9-12,21-30,33,35-38,41-43,46-49,52-56,59-62,65-68,71-76 and 79-83.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 21, 2009 has been entered.

Claims 6-8, 13-20, 31-32, 34, 39-40, 44-45, 50-51, 57-58, 63-64, 69-70, 77-78, and 84-85 have been cancelled. Consequently, claims 1-5, 9-12, 21-30, 33, 35-38, 41-43, 46-49, 52-56, 59-62, 65-68, 71-76, and 79-83 are pending in the instant application, of which claims 26-30, 33, 46-49, 52-56, 59-62, 65-68, 71-76, and 79-83 have been withdrawn from further consideration as being drawn to a non-elected invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent,

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except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. The rejection of claims 1-5, 9-12, 21-25, 35-38 and 41-43 under 35 U.S.C. 102(b) as being anticipated by Anderson et al in light of Heithoff et al is withdrawn in view of Applicants amendment.

2. The rejection of claims 1-5, 9-12, 21-25, 35-38, and 41-43 under 35 U.S.C. 102(a) & e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mahan et al in view of May et al is maintained.

Applicants are asserting that the Declaration by Mark Lawrence shows that dam activity was not even known to exist in *Pasteurella multocida* until it was discovered by Applicants. Applicants further assert that May et al does not even mention the dam gene. Finally, Applicants assert that Mahan does not disclose the limitation "comprising altered DNA adenine methylase (Dam) activity such that the bacteria are attenuated."

Applicants arguments have been fully considered, but are not found to be fully persuasive.

First, Applicants assert and have filed a Declaration by Mark Lawrence that shows that dam activity was not even known to exist in *Pasteurella multocida* until it was discovered by Applicants in 1999. However, while the Examiner would not disagree with this Declaration, it does not fully appreciate the disclosure of the prior art

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prior to Applicants earliest priority date, which is not 1999, but rather the filing date of the instant application (and associated provisional documents) which is 2003. As set forth previously, Mahan et al disclose of bacteria with altered DNA methylase activity (Dam). (See claim 1). Mahan et al further specifically claim the bacteria to be *Pasteurella multocida*. (See claim 12). Accordingly, based on the disclosure of Mahan et al one of ordinary skill in the art would be aware of the presence of the Dam gene in *P. multocida*, while this publication is after Applicants claim of first discovery in 1999, it is most importantly, prior to Applicants earliest entitlement to priority (Jan. 2003).

Second, Applicants assert that May et al does not even mention the dam gene. However, Applicants are respectfully directed to the Examples of Mahan. Examples 1-5 show attenuated *Salmonella* having Dam mutations, Example 6 shows attenuated *Vibrio* having Dam mutations, and Example 8 shows attenuated *Yersinia* having Dam mutations. Furthermore, Mahan et al disclose that DNA adenine methylases (Dam) “are **highly conserved** in many pathogenic bacteria that cause significant morbidity and mortality.” (Emphasis added; See detailed paragraph 123). Accordingly, one of skill in the art would be readily able to design a probe that would be able to identify the corresponding gene in *P. multocida* and readily isolated this gene. However, one of skill in the art need not even do this ordinary routine work in view of the disclosure of May et al. May et al (IDS ref BT) has sequenced the entire genome of *P. multocida*. Accordingly, one of ordinary skill in the art would merely need to run a computer sequence search of the known Dam genes against the genome of *P. multocida*, and a few seconds later would have the “highly conserved” gene contained within the *P.*

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multocida genome fully identified.

Finally, Applicants assert that Mahan does not disclose the limitation “comprising altered DNA adenine methylase (Dam) activity such that the bacteria are attenuated.” However, Applicants are respectfully directed to paragraph number 41, which sets forth that “the invention provides attenuated strains of pathogenic bacteria, said bacteria containing a mutation which alters Dam activity such that the bacteria are attenuated.” This in combination with the claims (e.g., claim 12) which define the pathogenic bacteria to specifically comprise *P. multocida*, discloses each and every limitation of the claims.

The claims are directed to an attenuated strain of a bacteria of the species *Pasteurella multocida*, said bacteria comprising altered DNA adenine methylase (Dam) activity such that the bacteria are attenuated.

Mahan et al (US Publication 2002/0068068) disclose of compositions containing pathogenic bacteria having non-reverting genetic mutations which alter activity of DNA adenine methylase (Dam) resulting in attenuation and methods of using these compositions to elicit an immune response to produce antibodies. (See abstract and claims). Mahan et al specifically set forth that the starting bacteria, to which a mutation of DNA adenine methylase was done, included *Pasteurella multocida*. (See detailed paragraph 88; and claims 11-12).

For reasons of record as well as the reasons set forth above, this rejection is maintained.

All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/  
Primary Examiner, Art Unit 1645  
January 26, 2010